

R E M A R K S

Claims 1-18 are in the application. Original claims are 1-15, and new claims 16-18 have been added. Support for claim 16 is in original claims 1, 2 and 12. Support for claim 17 is in claim 11. Support for claim 18 is in claim 13.

The Office Letter seems to contain several items, which form the basis for rejection. In this amendment, applicants' attorney responds to each item, and in the same order in which they appear in the Office Letter.

An Object of Applicants' Invention

As pointed out in the claims, and in the specification, an object of applicants' invention is:

The applicants' intent is "reducing the amount of adipose tissue at selected locations in the body"

[Claim 1, and cf. spec., page 1, lines 7-8.]

"In a single treatment reduction of the tissue from the original volume may range from 25% to 75% and higher"

[spec. page 2, lines 18-19]

Rejection under § 112 ¶ 1

Applicants believe the first point raised under § 112 is

"the fat is still present in the body ... unless the basal metabolism ... changes ... , the fat present in the body will be maintained at its present level and will be deposited in adipocytes, either remaining at the site or at other sites until metabolized. Applicant's themselves indicate that rats treated as claimed for 14 days gained weight".

[10/02/95 Office Letter,
Page 3, lines 11-15]

In response, nowhere do applicants indicate an intent to reduce the body's weight -- just to reduce the amount of adipose tissue at selected locations in the body. If that is done, it matters not where the fat goes or whether the patient gains or loses overall weight. The invention has utility as described.

The Office Letter speculates a lack of advantage or a disadvantage that is irrelevant. Applicants satisfy 35 U.S.C. 112 first ¶. The disclosure is adequate and enabling to accomplish what applicants say they want to accomplish. The Office may not propose a result different from that sought by applicants, and then postulate that such a proposed result will not happen.

The next point in the Office Letter is:

"Applicants themselves indicate that rats treated as claimed for 14 days gained weight".

[Office Letter, page 3,
lines 13-15]

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In response, the Office Letter quotation quoted above is a true statement; but "so what"? That tells absolutely nothing as to whether or not released fat stayed in the body.

The next point in the Office Letter is that applicants have failed to make any correlation between rats and:

"... cosmetic benefit as this is the intended result of the claimed invention".

[Office Letter, page 3,
lines 16-18]

In response, it is pointed out that applicants mention cosmetics, and it is well known that liposuction is often, or usually, conducted for cosmetic reasons. But, the intended result clearly stated by applicants is "reducing the amount of adipose tissue at selected locations in the body"; and applicants teach that "reduction of the tissue from the original volume may range from 25% to 75% and higher". The Office is not entitled to go beyond this.

The final point asserted in the Office Letter in support of the § 112 rejection is:

"Finally, the disclosure of Guidicelli et al. indicates that a rat model appears to be unable to predict efficiency in humans as it is clear from the reference that rat adipocytes react in a metabolically different manner from human

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adipocytes particularly when treated with
collagenase and trypsin."

[Office Letter, page 3
last two lines to page 4,
line 4]

In response thereto, applicants' attorney wishes to point out that what happens metabolically in the body is irrelevant to what applicants intend to do and do do, viz. reduce the amount of adipose tissue at selected locations in the body. Again, the Office Letter is engaged in an excursion beyond enabling disclosure and adequate written description.

Incidentally, Guidicelli et al. discloses that a mixture of collagenase plus trypsin "failed to affect the spontaneous rate of glycerol and free fatty acid released from both fat cells species" (rat and human). [Release of glycerol and free fatty acid is what happens when fat is hydrolyzed]. That response to stimulus by various biological entities were different matters not, again because what happens metabolically is irrevelant to applicants' invention.

Rejection under § 103

Claims 1-15 are rejected under 35 U.S.C. § 103 as being unpatentable over Lee et al. combined with Guidicelli et al. The rejection is respectfully traversed.

Lee et al. seem to teach the use of purified collagenase plus purified chymopapain to digest connective tissue. They teach that connective tissue contains not only collagen but also several other proteinaceous materials, hence the need for both collagenase and chymopapain. Object is to recover in vitro microvessel cells from the tissue. Another object is to digest connective tissue in vivo, and the following are mentioned (col. 8 l. 1-8):

"burns or ulcers, for intervertebral discolysis, for assisting in ophthalmic surgery, for the treatment of submucous fibrosis, for the treatment of Peyronie's disease, for the local enzymatic treatment of atherosclerotic plaques, and in the treatment and prevention of the development of familiar amyloiditic polyneuropathy (FAP)."

Lee et al. emphasize the use of liposuctioned fat for in vitro disruption and digestion of its connective tissue, thus permitting separation of viable microvessel cells from the digested tissue.

The heart of the rejection (Office Letter, page 5, last ¶ of the Office Action) is:

"Lee et al. ... discloses the effects of the claimed composition both in vitro and for in vivo application for the digestion of connective tissue wherever desired and as the claims call only for the reduction of adipose tissue [emphasis in the Office Letter], it would have been obvious and predictable to one of ordinary skill in the art to use conventional enzymes known to digest said tissue, regardless of its site and the expected digestion, i.e. dissociating the cells of the tissues [emphasis in the Office Letter]."

In response, it is noted that Lee et al. mention treatment of several conditions of the body, but when it comes to fatty tissue, it is mentioned only as being liposuctioned out of the body and then treated in vitro with the enzymes. Since liposuctioned fat is the only tissue specifically mentioned by Lee et al. as material for in vitro dissociation, and the only material they use in their working examples, it seems significant that they don't mention it in their list of conditions of the body to be treated. Thus, Lee ignores and teaches away from what applicants have discovered.

Applicants' attorney understands that some traditional liposuction surgeons routinely advise the patient before the

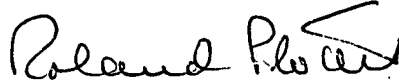
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surgery is performed that the surgery will contour or remove fat from a given area, but importantly, it will not cause overall weight loss. If the patient wishes to have overall weight loss, the solution is dieting rather than liposuction. In other words, the patient should understand, that after the contouring, if the patient does not watch the diet, there will be weight increase, and there will be no weight reduction. To achieve weight reduction, the patient should not, and cannot rely on liposuction, but must change diet and eating habits.

In summary, it is submitted that the specification and claims meet the requirements of Section 112; and for the reasons set forth above, distinguish over the art of record.

A Notice of Allowance is solicited.

Respectfully submitted,



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Certificate under 37 CFR 1.8(a)

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